

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application. The designation "original" is used to refer to the new claims presented in the preliminary amendment prior to examination of this application:

Claims 1 to 24 (cancelled by way of the preliminary amendment filed November 25, 2001).

Claim 25 (currently amended): A method of producing a product according to a process essentially controlled by a set of n parameters X_i affecting a set of k properties Y_j , characterizing the product, in which process at least some of said parameters X_i involved exhibit interfering effects on the desired properties Y_j , said method comprising:

- i) identifying an expected operational range of said process within which an optimal parameter value is likely to be found for each of said set of parameters X_i , and selecting given parameter data for obtaining experimentally associated property data;
- ii) assigning values to a set of k property weights w_j representing relative importance of said properties Y_j for the characterization of said product;
- iii) establishing a property behavior mathematical relations for each one of said set of k properties Y_j characterizing the product, said relation giving an estimated property values y_{e_j} for each said property Y_j in terms of said parameters X_i , within said range from given parameter data and associated property data, said given parameter data and associated property data being essentially statistically insufficient for the purposes of quantifying said property behavior mathematical relation in the case that said relation is to be used to find optimal parameter values for said process to be optimized for only one of said set of k properties Y_j characterizing the product;

- iii) using said property weights w_j and said property behavior mathematical relations for said set of k properties Y_j characterizing the product to establish a goal function in terms of property weighted deviations between the estimated properties Y_e , and corresponding specified goal values for said properties Y_i ;
- iv) minimizing the goal function to generate a set of n optimal parameter values for said parameters X_i , wherein said property behavior mathematical relations for said set of k properties Y_j characterizing the product are sufficient for the purposes of establishing said goal function; and
- vi) using said set of optimal parameter values in said process to produce said product.

Claim 26 (original): A method according to claim 25, wherein said product is a composition of matter, said set of optimal parameter values characterizing an optimal formulation for the composition.

Claim 27 (original): A method according to claim 26, wherein said product is a pharmaceutical product, said set of optimal parameter values characterizing an optimal formulation for the pharmaceutical product.

Claim 28 (currently amended): A method according to claim 25 53, wherein the values for said property weights w_j are obtained using an algorithm based on an analytic hierarchy process.

Claim 29 (original): A method according to claim 28, wherein said given property data are obtained through a number l of experimental runs of said process using said given parameter data, each said run using a distinct set of values for said given parameter data.

Claim 30 (original): A method according to claim 29, wherein said number of experimental runs of said process each uses a selected distinct set of values for said parameters X_i , covering substantially all extreme values within a chosen range of values for each one of said parameters X_i , wherein l is at least equal to $n + 1$ and is substantially less than a number used in the Fractional Factorial Matrix method.

Claim 31 (original): A method according to claim 27, wherein the values for said property weights w_j are obtained using an algorithm based on an analytic hierarchy process.

Claim 32 (original): A method according to claim 31, wherein said given property data are obtained through a number l of experimental runs of said process using said given parameter data, each said run using a distinct set of values for said given parameter data.

Claim 33 (original): A method according to claim 32, wherein said number of experimental runs of said process each uses a selected distinct set of values for said parameters X_i , covering substantially all extreme values within a chosen range of values for each one of said parameters X_i , wherein l is at least equal to $n + 1$ and is substantially less than a number used in the Fractional Factorial Matrix method.

Claim 34 (currently amended): A method according to claim 25 53, wherein said goal function is expressed as follows:

$$G(X_1, \dots, X_n) = \sum_{j=1}^k w_j^2 (Y_{e_j} - O_j)^2$$

wherein O_j are said specified goal values for said properties Y_j .

Claim 35 (original): A method according to claim 34, wherein said minimizing step is performed by successive iterations of:

$$G(X_1, \dots, X_n) = \sum_{i=1}^k [f_i(X_1, \dots, X_n)]^2.$$

Claim 36 (original): A method according to claim 35, wherein said goal function is minimized according to one or more specified ranges (a_i, b_i) wherein $a_i < X_i < b_i$, for one or more of said optimal parameter values.

Claim 37 (original): A method according to claim 25, further comprising the steps of:
performing experimentally said process using said set of optimal parameters values to obtain corresponding experimental values for said properties Y_j ;
ranking said set of optimal parameters values over predetermined alternative sets of parameters values for said X_i .

Claim 38 (original): A method according to claim 37, wherein said ranking step is performed using an algorithm based on an analytic hierarchy process.

Claim 39 (currently amended): A method according to claim 37, further including the step of:

incorporating said set of optimal parameters values and said corresponding experimental values for said properties Y_j respectively into said given parameter and associated property data;
repeating said steps ii) iii) to iv) v) to generate a new set of optimal parameters values for said parameters X_i .

Claim 40 (currently amended): A method of producing a product using optimized process parameter values, said process being essentially controlled by a set of n parameters X_i , characterizing a formulation for said product, n being greater than two, said parameters X_i , affecting a set of k properties Y_j , characterizing the product, in which process at least some of said parameters X_i involved exhibit interfering effects on the desired properties Y_j , said method comprising:

- a) conducting a number of l of experimental runs of said process each using a selected distinct set of values for said parameters X_i , covering substantially all extreme values within a chosen range of values for each one of said parameters X_i , wherein l is at least equal to $n + 1$ and is substantially less than a number used in the Fractional Factorial Matrix method, said chosen range corresponding to an expected operational range of said process within which an optimal parameter value is likely to be found for each of said set of parameters X_i ;
- b) measuring values for said properties Y_j characterizing the product in each of said l experimental runs, whereby parameter data and associated property data are obtained from said selected distinct set of values for said parameters X_i , and said measured values for said properties Y_j , respectively;
- c) determining an importance of said properties Y_j for the characterization of said product, comparing said importance of said properties Y_j relative to one another, and assigning values to a set of k property weights w_j , representing a relative importance of said properties Y_j for the characterization of said product;
- d) calculating a set of optimal parameter values for said parameters X_i , using said measured values for said properties Y_j and said assigned values of said set of k property weights w_j , and establishing property behavior mathematical relations giving estimated property values Y_{e_j} for each said property Y_j in terms of said parameters X_i within said chosen range from said parameter data and associated property data;
- e) using said property weights w_j and said property behavior mathematical relations for said set of k properties Y_j characterizing the product to establish a process goal function in terms of property weighted

deviations between the estimated properties Y_e_i and corresponding
specified goal values for said properties Y_i , wherein said property
behavior mathematical relations for said set of k properties Y_i
characterizing the product are sufficient for the purposes of
establishing said goal function;

minimizing the process goal function to generate a set of optimal
parameter values for said parameters X_i , and

- e) producing said product using said optimized process parameter values X_i ,
calculated in the previous step.

Claim 41 (original): A method according to claim 40, wherein said product is a pharmaceutical product, and said process is a formulation of said product.

Claim 42 (currently cancelled): A method according to claim 41, wherein said step of calculating comprises:

~~establishing property behavior mathematical relations giving an estimated property~~ Y_e_i ~~for each said property~~ Y_i ~~in terms of said parameters~~ X_i ~~from said parameter data and associated property data;~~
~~using said property weights~~ w_i ~~to establish a process goal function in terms of property weighted deviations between the estimated properties~~ Y_e_i ~~and corresponding specified goal values for said properties~~ Y_i ; and
~~minimizing the process goal function to generate a set of optimal parameter values for said parameters~~ X_i .

Claim 43 (currently amended): A method according to claim 42 41, wherein the values for said property weights w_i are obtained by an algorithm based on an analytic hierarchy process.

Claim 44 (original): A method according to claim 40, wherein $i = n + 1$.

Claim 45 (currently cancelled): A method according to claim 42, wherein $l = n + 1$.

Claim 46 (original): A method according to claim 43, wherein $l = n + 1$.

Claim 47 (currently amended): A method according to claim 41, wherein said goal function is expressed as follows:

$$\text{L} - G(X_1, \dots, X_n) = \sum_{j=1}^k w_j^2 (Y_{e_j} - O_j)^2$$

wherein O_j are said specified goal values for said properties Y_j .

Claim 48 (original): A method according to claim 47, wherein said minimizing step is performed through successive iterations.

Claim 49 (original): A method according to claim 48, wherein said goal function is minimized according to one or more specified ranges (a_i, b_i) wherein $a_i < X_i < b_i$ for one or more of said optimal parameters values.

Claim 50 (currently amended): A method according to claim 41, further comprising the steps of:

- f) performing experimentally said process using said set of optimal parameters values to obtain corresponding experimental values for said properties Y_j ;
- g) ranking said set of optimal parameters values over predetermined alternative sets of parameters values for said X_i .

Claim 51 (original): A method according to claim 50, wherein said ranking step is performed through an algorithm based on an analytic hierarchy process.

Claim 52 (currently amended): A method according to claim 41, further including the steps of:

- h) incorporating said set of optimal parameters values and said corresponding experimental values for said properties Y_j , respectively into said given parameter and associated property data;
- i) repeating said steps of conducting, measuring, establishing, using and minimizing a), b) and d) to generate a new set of optimal parameters values for said parameters X_i .

Claim 53 (new): A method according to claim 25, wherein n is greater than two.